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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,746	10/01/2001	Maurice Zauderer	1821.0060001/EKS/AJK	3613
28393	7590	12/16/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVE., N.W. WASHINGTON, DC 20005			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,746

Applicant(s)

ZAUDERER, MAURICE

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 6, and 7 are pending and under consideration in the present application.
2. Claims 1-7 were pending and rejected in the prior action mailed on July 13, 2004. In the Response filed on October 13, 2004, the Applicant amended claims 1-3, 6, and 7, and cancelled claim 5.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **(Prior Rejection- Maintained)** Claims 1-7 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the claimed method to identify potential vaccines for any infectious disease. The rejection is withdrawn from claim 5, which has been cancelled from the application. The claims have been amended to require that the host cell is a human host cell, and that the immune response must be a CTL response in human. The Applicant traverses the rejection on the by arguing that the teachings of the Veronese reference and the analogy made in the Hunt declaration provide support for the Applicant's

Art Unit: 1648

assertion that the claimed methods would be effective in the identification of vaccine targets against infectious diseases. These arguments are not found persuasive.

It is first noted that the rejection is not on the basis that the claimed method would not be able to identify host cell gene products that may induce a CTL response. Rather, the rejection is on the grounds that the Applicant has not demonstrated that such products would be useful as vaccines against an infectious disease. With this in mind, the teachings of the Veronese reference have been considered, but are not found persuasive in support of the Applicant's assertion. This reference has similar teachings to those of the Hickman and Herberts references described in the prior action, which indicate that it is simply unknown at present whether the induction of such responses may be useful in the treatment of the infection, or may result in further immunopathogenic responses. See, Veronese, page 2509 (first two paragraphs of the article text). Thus, the teachings of this reference fail to provide sufficient support to enable the identification host products as vaccine targets because the reference merely provides additional evidence as to the uncertainty in the effect of such CTL responses on the infected host.

The teachings of the Hunt declaration have been described in the prior action. The analogy made in the declaration between the treatment of cancers, and the activity of the present invention is noted. However, as was indicated in the prior action, such an analogy is not supported by the teachings of the art, or by any evidence presented by the Applicant. In view of this, the Declaration is still found unpersuasive.

The rejection is therefore maintained for the reasons of record and the reasons above.

Art Unit: 1648

5. **(Prior Rejection- Withdrawn)** Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, if it is assumed that the Applicant is enabled for methods wherein the step of screening for immunogenicity entails screening for the ability to induce a response in the host organism against the cell expressing said gene products, does not reasonably provide enablement for methods wherein the step involves only screening for immunogenicity in general. The claims have been amended to require that the host cell gene products are gene products of human cells, and that they are screened for their ability to induce a CTL response in humans. In view of this amendment requiring that the host cell gene products be screened for their ability to induce an immune response in the host organism, the rejection is withdrawn.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

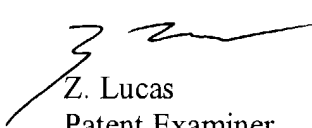
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1648

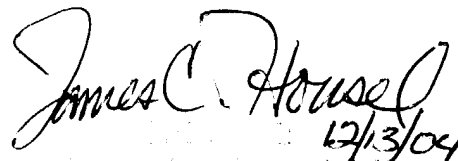
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



James C. Housel
12/13/04